

**Premarket Notification 510(k)**  
**ALBAzyme™ Papain Solution Kit**

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**Appendix 1**

**Premarket Notification 510(k)  
ALBAzyme™ Papain Solution Kit  
510(k) Summary (as required by 21 CFR 807.92(a))**

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**ALBAzyme™ Papain Solution Kit  
510(k) Summary (as required by 21 CFR 807.92(a))**

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**A.**

**Submitter:**

Alba Bioscience Limited (doing business as Quotient)

**Manufacturer and Manufacturing Site:**

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**Contact Person:**

Vittorio Borromeo, Senior Regulatory Affairs Officer

**Date:**

June 17<sup>th</sup>, 2014

**B.**

**Name of Device:**

ALBAzyme™ Papain Solution Kit

**Alba Bioscience Limited Product Code:**

Z317U

**Common Name:**

Solution, Stabilized Enzyme

**Proprietary Name:**

ALBAzyme™ Papain Solution Kit

**Device Class:**

The ALBAzyme™ Papain Solution Kit is a class II IVD medical device according to the stipulations of 21 CFR 864.9400.

**Regulation Number and Product Code:**

Regulation Number: 864.9400

US FDA Product Code: KSK

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**Classification Panel:**

Hematology

**C.**

**Predicate(s):**

The ALBAzyme™ Papain Solution Kit is Substantially Equivalent (SE) to the Immucor Gamma® Zyme-B product (510(k) Number: BK880016, Product Code: KSK).

**D.**

**Device Description:**

ALBAzyme™ Papain Solution Kit consists of two components:

- ALBAzyme™ Papain Solution – this is a papain enzyme solution supplied ready for use. This solution contains sodium azide (<0.1%), sodium meta-arsenite (0.02%) and bovine albumin. ALBAzyme™ Papain Solution is presented in 3 mL volumes in vials fitted with droppers.
- ALBAzyme™ Enzyme Control – this enzyme control solution is prepared by extracting *Glycine soja* lectin from soyabean seeds and diluting the extract in PBS (Phosphate Buffer Solution), bovine serum albumin and 0.1% weight/volume (w/v) sodium azide. ALBAzyme™ Enzyme Control solution is presented in 5 mL volumes in vials fitted with droppers.

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**E.**

**Indications for Use:**

ALBAzyme™ Papain Solution Kit is intended for use in the preparation and testing of papainized red blood cells.

**F.**

**Substantial Equivalence Comparison and Discussion:**

Table 1 below presents a direct comparison of the ALBAzyme™ Papain Solution Kit and the Immucor Gamma® Zyme-B product (510(k) Number: BK880016).

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**Table 1** – Comparison of ALBAzyme™ Papain Solution Kit and the Immucor Gamma® Zyme-B Product

	<b>ALBAzyme™ Papain Solution Kit</b>	<b>Immucor Gamma® Zyme-B Product</b>
<b>Device Classification Name</b>	Solution, Stabilized Enzyme	Solution, Stabilized Enzyme
<b>Product Code</b>	KSK	KSK
<b>US FDA Classification</b>	Class II	Class II
<b>US FDA Regulation Number</b>	864.9400	864.9400
<b>US FDA Review Panel</b>	Hematology	Hematology
<b>Intended use</b>	ALBAzyme™ Papain Solution Kit is used for the preparation and testing of papainized red blood cells.	The Immucor Gamma® Zyme-B product is a Bromelin solution for one-stage test procedure.
<b>Intended Use Clarification</b>	The ALBAzyme™ Papain Solution is used to treat human red blood cells with papain for use in <i>in vitro</i> immunohematology assays, and the ALBAzyme™ Enzyme Control reagent is for the quality control of papainized red blood cells prior to use.	Bromelin solution for one-stage test procedure.
<b>Intended User(s)</b>	<i>In vitro</i> diagnostic (IVD) device for professional use only.	IVD device for professional use only.
<b>Reagent</b>	2-vial kit, one vial each of Papain Solution (1 x 3mL) and Enzyme Control (1 x 5mL).	1-vial of Bromelin Solution (1 x 10mL).
<b>Enzyme Component/Type</b>	Papain - Proteolytic Enzyme	Bromelin - Proteolytic Enzyme
<b>Control Type</b>	<i>Glycine soja</i> Lectin	Not Applicable
<b>No. of Vials</b>	2	1
<b>Trade Dress</b>	Alba Bioscience Limited (doing business as Quotient)	Immucor, Inc.

From Table 1 above, it can be ascertained that the ALBAzyme™ Papain Solution Kit and the Immucor Gamma® Zyme-B product are substantially equivalent with regards to the following parameters; classification, intended use and mode of action. Each product contains a proteolytic enzyme, Papain in the case of the ALBAzyme™ Papain Solution Kit, and Bromelin in the Immucor Gamma® Zyme-B product. Being of

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the same enzyme type, the Bromelin and Papain each have the same mode of action.

Comparator Testing was performed over 4 trial sites and this data is presented, and discussed fully, in sections 18, 'Performance Testing –Bench' and 20, 'Performance Testing – Clinical' (and their associated Appendices) of this 510(k) submission. However, the results produced from these comparator studies confirmed that the ALBAzyme™ Papain Solution Kit, is comparable to the Immucor Ficin Solution and Ficin Control reagents of the Immucor Panocell®-10, Ficin-Treated product, with regards to efficacy for the intended purpose of preparation and testing of enzyme-treated red blood cells.

The ALBAzyme™ Papain Solution Kit contains 2 vials as does the Ficin Solution and Ficin Control contained within the Immucor Panocell®-10 (Ficin-Treated) product, which is a 24-vial kit. These additional components are not essential for use with the Immucor Ficin Solution or Ficin Control and are unrelated to the components of the ALBAzyme™ Papain Solution Kit. Consequently, the provision of these additional reagents with the Immucor product has no impact on the substantial equivalence claimed between the ALBAzyme™ Papain Solution Kit and the Ficin Solution and Ficin Control contained within the Immucor Panocell®-10 (Ficin-Treated) product.

**G.**

**Performance Testing**

Performance evaluation of the ALBAzyme™ Papain Solution Kit was undertaken at 4 trial sites; Quotient (Edinburgh), Blood Center Wisconsin (BCW), Memorial Blood Center (MBC) and New York Blood Center (NYBC).

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The internal testing at Quotient carried out two studies to demonstrate Substantial Equivalence to a US predicate and to demonstrate reproducibility form Lot to Lot, Occasion to Occasion and Operator to Operator.

The three external trial sites undertook a comparator study to demonstrate substantial equivalence between the ALBAzyme™ Papain Solution Kit and its US predicate. Each trial site tested 100 red blood cell samples in total. The samples were tested with the enzyme control from the trial kit and the predicate respectively and prior to enzyme treatment and result were taken. All samples, trial and predicate, gave negative results. The red blood cell samples were treated with the trial enzyme solution (ALBAzyme™ Papain Solution) and the predicate enzyme solution (Ficin Solution) respectively. Testing was performed with the respective enzyme control reagent to confirm treatment of the red blood cells. Reaction grades for the red blood cells treated with the trial and the predicate enzyme solution gave comparable grades when tested with the control reagents. No discrepancies were noted by any of the 4 trial sites.

These results indicated that the ALBAzyme™ Papain Solution Kit and the Ficin Solution and Ficin Control contained within the Immucor Panocell-10, Ficin-Treated product, are substantially equivalent with regards to efficacy when used as intended by the manufacturer. The results of these studies are presented and discussed fully in 'Performance Evaluation Report: Papain Solution Kit, Product Code Z317U, PE13-P0119-RPT', and 'Internal Performance Evaluation Report: Papain Solution Kit, Product Code Z317U, PE13-P0119-INT-RPT' which are included as Appendices 10 and 11 (respectively) of this 510(k) submission.

To demonstrate the 'Lot to Lot' reproducibility and reliability of the ALBAzyme™ Papain Solution Kit, Quotient subjected 3 lots of the kit to testing by three different operators over a minimum period of 5 (non-consecutive) days with a test panel of three red blood cell samples.

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Test results obtained highlighted that the ALBAzyme™ Papain Solution Kit performs reliably and results are reproducible from lot to lot of product. These comparator studies and the results obtained for the 'Lot to Lot' Reproducibility study are presented and discussed fully in 'Internal Performance Evaluation Report: Papain Solution Kit, Product Code Z317U, PE13-P0119-INT-RPT' and 'Performance Evaluation Report: Papain Solution Kit, Product Code Z317U, PE13-P0119-RPT', which are included as Appendices 10 and 11 (respectively) of this 510(k) submission.

Performance Evaluation testing conducted at the 4 trial sites with the ALBAzyme™ Papain Solution Kit, confirmed that this kit is substantially equivalent with regards to efficacy, as the Ficin Solution and Ficin Control contained within the Immucor Panocell®-10, Ficin-Treated predicate device. Furthermore, the internal 'Lot to Lot' study conducted, highlighted that the ALBAzyme™ Papain Solution Kit performs reliably and results obtained are reproducible, confirming that this product is suitable for its intended use, to perform and confirm enzyme treatment of red blood cells (as stated in the Instructions for Use for this product).

## **H.**

### **Summary of Software**

The ALBAzyme™ Papain Solution Kit has not been designed with any software device components or accessories, nor is it intended to be used in combination with any software device. Consequently, this section is not applicable to the ALBAzyme™ Papain Solution Kit as this device does not require software to fulfil its intended use (as stipulated in the Instructions for Use for this device).

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**I.****Compliance with FDA Guidance and Consensus Standards**

The ALBAzyme™ Papain Solution Kit has not been designed or manufactured in conjunction with any US FDA consensus standards.

**J.****Conclusion**

The ALBAzyme Papain Solution Kit is a Class II IVD medical device according to the stipulations of 21 CFR 864.9400. This product is substantially equivalent, to US-legally marketed predicate, the Immucor Gamma® Zyme-B product (510(k) Number BK880016).

Substantial equivalence has also been demonstrated via comparator studies conducted at 4 discrete trial sites and subsequent analysis of results obtained (please refer to section G above).

Performance Evaluation studies have also confirmed that the ALBAzyme™ Papain Solution Kit is 'fit for purpose', i.e. is suitable for its intended use, as stated in the Instructions for Use for this device. No issues with safety or effectiveness are anticipated for this device.